# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Kouji WAKI et al

Serial No.:

10/580,100

Filed:

May 19, 2006

Title:

**ULTRASONOGRAPH** 

Group:

3768

Examiner:

Hien Ngoc NGUYEN

Confirmation No.:

5080

### **AMENDMENT**

Mail Stop: AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

November 4, 2010

Sir:

In response to the Office Action dated August 4, 2010, please amend the above-identified application as listed below and as set forth on the following pages:

Amendments to the claims begin on page 2;

Remarks are included beginning on page 7; and

Authorization is included on page 16.

#### AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior listings, and all prior versions, of claims in the application.

### **LISTING OF CLAIMS**:

 (Currently Amended) An ultrasonic imaging apparatus comprising: an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

ultrasound an ultrasound image structuring means that unit configured to generates generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

elastic an elastic image structuring means that unit configured to obtains

obtain a strain or an elastic modulus of the elasticity of the object of a region

corresponding to the ultrasound image on the basis of the reflected echo signal and
generates a color elastic image;

display a display means that configured to everlays overlay the ultrasound image to the color elastic image, or arranges arrange the ultrasound image and the color elastic image and displays the resultant image on a screen; and

setting means that a setting unit configured to variably sets variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and the level of the strain or elastic modulus, wherein

the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus.

Docket No. 389.46211X00 Serial No. 10/580,100 Office Action dated August 4, 2010

- 2. (Currently Amended) An ultrasonic imaging apparatus according to Claim 1, wherein the corresponding relationship between the hue of the color elastic image and the level of the strain or elastic modulus set by the setting means unit is displayed on the screen with a color bar.
- 3. (Previously Presented) An ultrasonic imaging apparatus according to Claim 2, wherein, with the color bar, a large amount of the strain or the elastic modulus and a small amount of the strain or the elastic modulus are displayed with different hues and the boundary between the hue having the large amount of the strain or the elastic modulus and the hue having the small amount of the strain or the elastic modulus is displayed with another hue.
- 4. (Currently Amended) An ultrasonic imaging apparatus according to Claim 3, wherein the boundary between the hue having the large amount of the strain or the elastic modulus and the hue having the small amount of the strain or the elastic modulus is movably formed with the setting meansunit.
- (Currently Amended) An ultrasonic imaging apparatus according to Claim
   wherein a boundary region of the hue different from the hue of the periphery is
   settably formed at an arbitrary position of the color bar with the setting meansunit.
  - 6. (Cancelled).
- 7. (Previously Presented) An ultrasonic imaging apparatus according to Claim 1, wherein the color elastic image has a peripheral region including a setting

Docket No. 389.46211X00 Serial No. 10/580,100 Office Action dated August 4, 2010

value of the amount of the strain or the elastic modulus with the hue different from the hue of another region.

- 8. (Previously Presented) An ultrasonic imaging apparatus according to Claim 7, wherein the hue of the peripheral region has a tone in accordance with the level of the amount of the strain or the elastic modulus.
- 9. (Currently Amended) An ultrasonic imaging apparatus according to Claim 1, wherein the elastic image structuring means unit comprises:

a color conversion table that is rewritable and sets a relationship between the level of the amount of the strain or the elastic modulus and the color of the color elastic image;

calculating means that a calculator configured to calculate an amount of the strain or the elastic modulus of the elasticity of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and; and

to read the color corresponding to the obtained amount of the strain or the elastic modulus from the conversion table and generates-generate a color elastic image indicating the distribution of physical quantities, and

wherein the color conversion table is rewritten in accordance with an instruction input from the setting meansunit.

10. (Currently Amended) An ultrasonic imaging apparatus according to Claim 9, wherein the elastic image structuring means-unit displays, on the screen of the display meansunit, a color bar indicating a corresponding relationship between

the level of the amount of the strain or the elastic modulus and the hue of the color elastic image, set to the color conversion table.

11. (Currently Amended) An ultrasonic imaging apparatus comprising: an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

ultrasound an ultrasound image structuring means that unit configured to generates generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

elastic-image an elastic-image structuring means that unit configured to obtains obtain a strain or an elastic modulus of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generates generate a color elastic image; and

display a display means that overlays configured to overlay the ultrasound image to the color elastic image, or arranges arrange the ultrasound image and the color elastic image and displays the resultant image on a screen,

wherein the strain or the elastic modulus is calculated from the amount of motion of the tissue, and the display means-unit displays a color bar indicating a correspondence between the hue of the color elastic image and the strain or the elastic modulus.

12. (Original) An ultrasonic imaging apparatus according to Claim 11, wherein a character indicating the assignment of the hardness of the color elastic image is displayed around the color bar.

Docket No. 389.46211X00 Serial No. 10/580,100 Office Action dated August 4, 2010

- 13. (Currently Amended) An ultrasonic imaging apparatus according to Claim 1, wherein the color elastic image is displayed alternatively a larger region or a smaller region than the setting strain or elastic modulus with a set huefor at least one of a hard region with a high elastic modulus and a soft region with a low elastic modulus.
  - 14. (New) An ultrasonic imaging apparatus comprising:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic image structuring unit configured to obtain a strain or an elastic modulus of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generate a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arranges the ultrasound image to the color elastic image and display the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or the elastic modulus, wherein

the setting unit assigns the hue of the color elastic image so as to prevent the display from displaying a neutral portion in a color conversion table.

#### **REMARKS**

### I. <u>Introduction</u>

By the present Amendment, claims 1, 2, 4, 5, 9-11, and 13 have been amended. Claim 14 is newly presented for consideration. Accordingly, claims 1-5 and 7-14 are now pending in the application. Claims 1, 11, and 14 are independent.

# II. Office Action Summary

In the Office Action of August 4, 2010, claims 1, 9-11, and 13 were rejected under 35 USC §112, second paragraph, as being indefinite. Claims 1 and 9 were rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 6,068,597 issued to Lin. Claims 2-5, 7, 8, and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lin in view of U.S. Patent Application No. 2004/0234113 to Miga. Claims 11-13 appear to have been rejected under 35 USC §103(a) as being unpatentable over Lin in view of Miga (although this is not clearly indicated in the Office Action). These rejections are respectfully traversed.

#### III. Improper Finality

At the outset, Applicants respectfully submit that the finality of the instant Office Action appears to be improper, and consequently, should be withdrawn. Applicants note that new references have been applied to reject the claims, and these references were not previously of record. The amendments to the claims were not intended to define over the reference, but rather to address the issues of indefiniteness raised in the Office Action. The reference to Matsumura did not qualify as prior art under §102(e), thereby rendering the rejection improper. Additionally, Applicants note that the Office Action indicates that the previously

submitted arguments were persuasive in overcoming the rejection predicated on Matsumura and Suzuki. Thus, it appears that a new Non-Final Office Action should have been issued instead.

Applicants, therefore, respectfully request withdrawal of the finality of the instant Office Action.

### IV. Rejections under 35 USC §112

Claims 1, 9-11, and 13 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Regarding this rejection, the Office Action cites a passage in the claims, and indicates that it is not understood what is being claimed. Applicants note, however, that the passage cited in the Office Action was previously cancelled from the claims.

Claims 1 and 9-11 were also indicated as being indefinite because the term "means" was recited instead of "means for". The Office Action indicated that it was unclear whether §112, 6<sup>th</sup> paragraph, was being invoked or not. By the present Amendment, Applicants have amended the claims, in part, to address this rejection by removing the term "means" from the claims. Accordingly, it should be sufficiently clear that §112, 6<sup>th</sup> paragraph, is not being invoked.

Withdrawal of this rejection is therefore respectfully requested.

# V. Rejections under 35 USC §102

Claims 1 and 9 were rejected under 35 U.S.C. §102(a) as being anticipated by Lin. Regarding this rejection, the Office Action indicates that Lin discloses an ultrasonic imaging apparatus that includes an ultrasonic probe that receives and sends ultrasonic waves from/to an object, ultrasound image structuring that

generates an ultrasound image on the basis of a reflected echo signal, elastic image structuring that obtains a strain or an elastic modulus of the elasticity of the object, and generates a color elastic image. The Office Action goes on to assert that Lin discloses a display that overlays the ultrasound image to the color elastic image or arranges the ultrasound image and the color elastic image and displays the resultant image on a screen, setting means for variably setting a corresponding relationship between a hue of the color elastic image displayed on the screen and the level of strain or elastic modulus, a calculating means for calculating the strain or elastic modulus of a region corresponding to the ultrasound image based on the reflected echo signal, and a color conversion table that sets a relationship between the level of the strain or elastic modulus and the color of the color elastic image. The Office Action goes on to assert a color image generating means that reads the color corresponding to the obtained strain or elastic modulus from the conversion table and generates a color elastic image indicating the distribution of the strain or elastic modulus. Applicants respectfully disagree.

As amended, independent claim 1 defines an ultrasonic imaging apparatus that comprises:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic image structuring unit configured to obtain a strain or an elastic modulus of the elasticity of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generates a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arrange the ultrasound image and the color elastic image and displays the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and the level of the strain or elastic modulus, wherein

the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus.

The ultrasonic imaging apparatus of independent claim 1 includes an ultrasonic probe that receives and sends ultrasonic waves from/to an object, an ultrasound image structuring unit configured to generate an ultrasound image based on a reflected echo signal that is received by the ultrasonic probe, and an elastic image structuring unit configured to obtain a strain or an elastic modulus of the object in a region corresponding to the ultrasound image based on the reflected echo signal and generate a color elastic image. The ultrasonic imaging apparatus also includes a display configured to overlay the ultrasound image to the color elastic image or arrange the ultrasound image and the color elastic image, and subsequently display the resultant image on a screen. A setting unit is also configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or elastic modulus. According to independent claim 1, the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus then a preset amount of the strain or the elastic modulus. According to the features of independent claim 1, the setting unit is configured to set a preset physical value so that a user, such as a medical doctor, can easily detect a harder region (suspected of being cancerous) than the present value and also detect certain regions having a desired elastic modulus.

The Office Action alleges that Lin discloses all of the features recited in independent claim 1. This does not appear to be the case. Lin discloses a vibrational resonance ultrasonic Doppler spectrometry device capable of producing characteristic vibrational resonance spectra of soft structures in compressible media or soft tissues in a living body. An audio frequency source is used to apply a sequence of vibrational frequencies into the body while ultrasonic pulsed Doppler beams are focused at various locations within a region of interest. The received Doppler signals are then used to estimate the amplitude of the vibrational resonance response at each location. A vibrational resonance spectrum is then computed from the received Doppler amplitudes at each vibrational frequency and graphically displayed.

Contrary to the assertions made in the Office Action, Lin does not generate a color image corresponding to the distribution of the strain or elastic modulus. Rather, Lin appears to map the vibrational resonance spectra of the plurality of regions of interest into colors and brightness according to a specific curve shape criteria. The Office Action identifies reference numerals 136 and 138 as corresponding to the displayed color elastic image. Reference numerals 136 and 138, however, merely identify a spectrum processor and monitor, respectively. The cited passage goes on to indicate that the color mapper (136) loads the lookup table (856) using previously received color mapping commands from the control interface. The color window limits can then be adjusted according to the ranges of index values generated by the curve shape estimator. The encoded values at each pixel in the vibrational resonance ultrasonic Doppler image are then mapped into color lights using the lookup table and displayed on the monitor. There is no disclosure or suggestion for displaying the color elastic image with specific hue values

corresponding to a relationship between the strain or elastic modulus that is measured to a preset amount.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 1-5 and 7-10 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

#### VI. Rejections under 35 USC §103

Claims 11-13 were rejected under 35 USC §103(a) as being unpatentable over Lin in view of Miga. Regarding this rejection, the Office Action alleges that Lin discloses an ultrasonic imaging apparatus that includes strain or elastic modulus calculated from the amount of motion of the tissue. Miga is relied upon for disclosing a color bar indicating a correspondence between the hue of the color elastic image and the strain or elastic modulus, as well as a character indicating the assignment of the hardness of the color image displayed around the color bar. Miga is further relied upon for disclosing the color elastic image being displayed alternatively as a larger region or a smaller region than the setting strain or elastic modulus with a set hue. Applicants respectfully disagree.

As amended, independent claim 11 defines an ultrasonic imaging apparatus that comprises:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic-image structuring unit configured to obtain a strain or an elastic modulus of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generate a color elastic image; and

a display configured to overlay the ultrasound image to the color elastic image, or arrange the ultrasound image and the color elastic image and displays the resultant image on a screen,

wherein the strain or the elastic modulus is calculated from the amount of motion of the tissue, and the display unit displays a color bar indicating a correspondence between the hue of the color elastic image and the strain or the elastic modulus.

According to at least one feature of independent claim 11, the strain or the elastic modulus is calculated from the amount of motion of the tissue, and the display is configured to display a color bar indicating a correspondence between the hue of the color elastic image and the strain or the elastic modulus.

The Office Action alleges that the combination of Lin and Miga discloses all of the features recited in independent claim 11. In particular, Miga is relied upon for disclosing a color bar that indicates a correspondence between the hue of the color elastic image and the strain or elastic modulus. Applicants' review of this reference, however, suggests otherwise. Miga discloses an elastography imaging system for characterizing properties of tissue wherein an image reconstruction algorithm acquires a preoperative imaging volume and a second imaging sequence after deformation has been applied. A computational model is generated and boundary conditions are derived from a pre-post deformation comparison as well as information gathered from the deformation source application.

Miga only appears to disclose a distribution of Young's modulus in Fig. 2C and a representation of the computational domain used for the simulation in Fig. 2B. Miga indicates that the highest material property corresponds to invasive ductal carcinoma, while the mid-level stiffness corresponds to that of fibrous tissue with a

general background corresponding to that of normal fat. Miga never discloses or suggests calculating the strain or elastic modulus from the amount of motion of the tissue and displaying a color bar indicative of a correspondence between the hue of the color elastic image and the strain or the elastic modulus.

It is therefore respectfully submitted that independent claim 11 is allowable over the art of record.

Claims 12 and 13 depend from independent claim 11, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 11. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

Independent claim 14 is newly presented and defines an ultrasonic imaging apparatus that comprises, in part:

the setting unit assigns the hue of the color elastic image so as to prevent the display from displaying a neutral portion in a color conversion table.

According to this feature, the setting unit assigns the hue of the color elastic image so that the display is prevented from displaying a neutral portion in a color conversion table. Applicants' review of the cited references has failed to reveal any disclosure or suggestion for such features.

It is therefore respectfully submitted that independent claim 14 is allowable over the art of record.

# VII. <u>Conclusion</u>

For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

### **AUTHORIZATION**

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 389.46211X00).

Respectfully submitted,
ANTONELLI, TERRY, STOUT & KRAUS, LLP.

/Leonid D. Thenor/ Leonid D. Thenor Registration No. 39,397

LDT/vvr 1300 N. Seventeenth Street Suite 1800 Arlington, Virginia 22209 Tel: 703-312-6600

Fax: 703-312-6666

Dated: November 4, 2010